



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
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Washington, D.C. 20231

JUL 29 1999

David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Dear Mr. Read:

The attached application for patent term extension of U.S. Patent No. 5,362,755 was filed on May 21, 1999, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, XOPONEX® (levalbuterol hydrochloride), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156 IF the approval of XOPONEX® (levalbuterol hydrochloride) is considered the first permitted use of levalbuterol hydrochloride, or a salt or ester thereof. As noted in the application, albuterol has been previously approved and albuterol contains levalbuterol hydrochloride. See also the Prescription Drug Product List, Page 3-10, Approved Drug Products with Therapeutic Equivalence Evaluations, 18th Edition, attached. In addition, the posting on FDA's home page (<http://www.fda.gov/cder/da/da0399.HTM>) for the approval of XOPONEX indicates that the approval of levalbuterol hydrochloride the approval of a new formulation (a new dosageform or new formulation of an active ingredient already on the market) and not a new drug. See attachment 2.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)308-6916 (facsimile).

Karin Tyson
Senior Legal Advisor/Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: HAROLD C. WEGNER
FOLEY & LARDNER
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WASHINGTON DC 20007-5109

Attachment #1

PRESCRIPTION DRUG PRODUCT LIST

3-10

ALBENDAZOLE

TABLET, ORAL
ALBENZA
+ SMITHKLINE BEECHAM 200MG

N20666 001
JUN 11, 1996

ALBUTEROL

AEROSOL, METERED; INHALATION

ALBUTEROL
MEDISOL
0.09MG/INH

N74072 001
AUG 01, 1996
N73272 001
DEC 28, 1995

ALBUMIN CHROMATED CR-51 SERUM

INJECTABLE; INJECTION
CHROMALBIN
ISO TEX 100 ucl/VIAL

N17835 001

AB
NORTON WATERFORD
0.09MG/INH

N17559 001
N18473 001

ALBUMIN HUMAN

INJECTABLE; INJECTION
OPTISON
+ MOLECULAR BIOSYSTEMS 10MG/ML

N20899 001
DEC 31, 1997

AEROSOL, METERED; INHALATION
PROVENTIL-HEA
+ 3M

EQ 0.09MG BASE/INH

N20503 001
AUG 15, 1996

ALBUMIN IODINATED I-125 SERUM

INJECTABLE; INJECTION
RADIOIODINATED SERUM ALBUMIN (HUMAN) IHS A I 125
MALLINCKRODT 6.67 ucl/ML
10 ucl/ML
100 ucl/ML

N17844 003
N17844 001
N17844 002

CAPSULE; INHALATION
VENTOLIN ROTACAPS
+ GLAXO WELLCOME

EQ 0.2MG BASE

N19489 001
MAY 04, 1988

ALBUMIN IODINATED I-131 SERUM

INJECTABLE; INJECTION
MEGATOE
ISO TEX 0.5mcl/VIAL
1mcl/VIAL

N17837 001
N17837 002

SOLUTION; INHALATION
ALBUTEROL SULFATE
ALPHARMA

EQ 0.083% BASE

N73533 001
SEP 26, 1995
N73495 001

AN
COBLEY PHARM

EQ 0.083% BASE

MAY 28, 1993
N73307 001

AN
DEY

EQ 0.5% BASE

NOV 27, 1991
N72652 001

AN
NEPHRON

EQ 0.083% BASE

FEB 21, 1992
N74880 001

AN
PROVENTIL
+ SCHERING

EQ 0.083% BASE

SEP 17, 1997
N19243 002

AN
+ SCHERING

EQ 0.5% BASE

JAN 14, 1987
N19243 001

AN
+

EQ 0.5% BASE

JAN 14, 1987

AEROSOL, METERED; INHALATION

ALBUTEROL
ALPHARMA 0.09MG/INH

N73045 001
AUG 19, 1997
N72273 001

AN
+ GLAXO WELLCOME

EQ 0.083% BASE

N19773 001
APR 23, 1992
N19269 002

AB
MEDEVA 0.09MG/INH

AUG 14, 1996

AN
+

EQ 0.5% BASE

JAN 16, 1987

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Drug Approvals for March 1999

Definitions and Notes

March 1999

Original New Drug Applications

Original Application #: 020966

Approval Date: 30-MAR-99

Trade Name: SPORANOX

Chemical Type: 3

Therapeutic Potential: S

Dosage Form: INJECTABLE

Applicant: JANSSEN RESEARCH FDN DIV JOHNSON AND JOHNSON

Active Ingredient(s): ITRACONAZOLE

OTC/RX Status: RX

Indication(s): For the treatment of blastomycosis, histoplasmosis and aspergillosis in immunocompromised and non-immunocompromised patients

Original Application #: 020908

Approval Date: 26-MAR-99

Trade Name: VAGIFEM

Chemical Type: 3

Therapeutic Potential: S

Dosage Form: TABLET

Applicant: NOVO NORDISK PHARMACEUTICAL INC

Active Ingredient(s): ESTRADIOL

OTC/RX Status: RX

Indication(s): For the relief of postmenopausal atrophic vaginitis due to estrogen deficiency

Original Application #: 020837

Approval Date: 25-MAR-99

Trade Name: XOPENEX

Chemical Type: 3

Therapeutic Potential: S

Dosage Form: SOLUTION

Applicant: SEPRACOR PHARMACEUTICALS

Active Ingredient(s): LEVALBUTEROL HYDROCHLORIDE

OTC/RX Status: RX

Indication(s): For the treatment or prevention of bronchospasm in adults and adolescents 12 years of age and older with reversible obstructive airway disease

Original Application #: 020992

Approval Date: 24-MAR-99

Trade Name: CENESTIN

Chemical Type: 3

Therapeutic Potential: S

Dosage Form: TABLET

Applicant: DURAMED PHARMACEUTICALS INC

Active Ingredient(s): ESTROGENS, CONJUGATED

OTC/RX Status: RX

Indication(s): For use in the treatment of moderate-to-severe vasomotor symptoms associated with the menopause

Original Application #: 020612

Approval Date: 19-MAR-99

Trade Name: LIDODERM

Chemical Type: 3

Therapeutic Potential: S

Dosage Form: FILM, EXTENDED RELEASE

Applicant: HIND HEALTH CARE

Active Ingredient(s): LIDOCAINE

OTC/RX Status: RX

Indication(s): For the treatment of pain in post-herpetic neuralgia

Original Application #: 020980

Approval Date: 09-MAR-99

Trade Name: LAMISIL

Chemical Type: 6

Therapeutic Potential: S

Dosage Form: EMULSION, CREAM

Applicant: NOVARTIS PHARMACEUTICALS CORP

Active Ingredient(s): TERBINAFINE HYDROCHLORIDE

OTC/RX Status: OTC

Indication(s): For the treatment of tinea pedis (athlete's foot), tinea cruris (jock itch) and tinea corporis (ringworm) due to Epidermophyton floccosum, Trichophyton mentagrophytes and Trichophyton rubrum

Original Application #: 020994